Application No.: 09/634,399

Office Action Dated: November 30, 2005

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application. Listing of Claims:

1. (**Previously Presented**) A composition in the form of a single-phase gel comprising from about 5% to about 8% minoxidil, a crosslinked copolymer of acrylic acid as a thickening agent, and a pharmaceutically acceptable solvent, wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition.

2 - 4. (**Cancelled**)

- 5. (**Previously Presented**) A composition of claim 1 which comprises from about 5% to about 6% minoxidil.
- 6. (Original) A composition of claim 5 which comprises about 5% minoxidil.
- 7. (**Previously Presented**) A composition of claim 1, wherein said pharmaceutically acceptable solvent is selected from the group consisting of ethanol, propanol, butanol, propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, glycerol and mixtures thereof.
- 8. (**Previously Presented**) A composition of claim 7, comprising a solvent selected from the group consisting of ethanol, propanol and butanol.
- 9. (Canceled)
- 10. (**Previously Presented**) A composition of claim 8, comprising a solvent selected from the group consisting of ethanol and isopropanol.
- 11. (Canceled)
- 12. (Canceled)

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- 13. **(Previously Presented)** A composition of claim 7, comprising a solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.
- 14 (**Previously Presented**) A composition of claim 13, wherein said solvent comprises propylene glycol.
- 15. (**Previously Presented**) A composition of claim 7, wherein said solvent comprises a mixture comprising a first solvent selected from the group consisting of ethanol, propanol and butanol and a second solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.
- 16. (**Original**) A composition of claim 15, wherein said solvent comprises a mixture of ethanol and propylene glycol.
- 17. (Original) A composition of claim 1, further comprising a neutralizing agent.
- 18. (**Original**) A composition of claim 17, wherein said neutralizing agent is selected from the group consisting of ammonium hydroxide, arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, sodium hydroxide, and potassium hydroxide.
- 19. (**Original**) A composition of claim 18, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine.

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- 20. (**Original**) A composition of claim 19, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.
- 21. (Original) A composition of claim 1, wherein said solvent is present in said composition in an amount of at least about 20%.
- 22. (Previously presented) A composition of claim 21 which comprises from about 20% to about 99% of said solvent.
- 23. (Canceled)
- 24 29. (Cancelled)
- 30. (Previously presented) A composition of claim 1, wherein said crosslinked copolymer of acrylic acid comprises an acrylate/ C_{10-30} alkyl acrylate crosspolymer.
- 31 34. (Cancelled)
- 35. (Previously presented) A composition of claim 30 wherein said solvent is present in said composition in an amount of at least about 20%.
- 36 61. (Cancelled)
- 62. (**Previously Presented**) A composition in the form of a single-phase gel comprising: from about 5% to about 8% of minoxidil;

from about 30% to about 80% of a first solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol;

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from about 10% to about 50% a second solvent selected from the group consisting of ethanol, propanol and butanol;

from about 0.01% to about 50% of a crosslinked copolymer of acrylic acid; from about 0% to about 3% of a neutralizing agent; and water (qs);

wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition.

(Cancelled) 63 - 65.

- (Previously Presented) A composition of claim 62, wherein said first solvent is 66. propylene glycol.
- 67. (Canceled)
- 68. (Previously Presented) A composition of claim 62, wherein said second solvent is selected from the group consisting of ethanol and isopropanol.
- 69. (Canceled)
- 70. (Previously presented) A composition of claim 62 wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.
- 71. (Original) A composition of claim 62, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-secbutanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine,

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tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.

- 72. (**Original**) A composition of claim 71, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine, and mixtures thereof.
- 73. (**Original**) A composition of claim 72, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.
- 74. (Previously Presented) A composition of claim 62, comprising:

from about 5% to about 7% of minoxidil;

from about 40% to about 70% of said first solvent;

from about 20% to about 30% of said second solvent;

from about 0.05% to about 3% of a crosslinked copolymer of acrylic acid; and from about 0.03% to about 1% of a neutralizing agent.

75. (Previously Presented) A composition of claim 74, comprising:

from about 5% to about 6% of minoxidil;

from about 50% to about 60% of said first solvent; and

from about 25% to about 30% of said second solvent.

76. (**Previously Presented**) A composition of claim 74 comprising:

about 5% of minoxidil;

about 53% of said first solvent; and

about 26% of said second solvent;

from about 0.25% to about 1% of a crosslinked copolymer of acrylic acid; and from about 0.15% to about 0.6% of a neutralizing agent.

77 – 110. (Cancelled)

- (Previously presented) A method comprising topically administering a composition 111. according to claim 1 to a region of hair loss on a patient.
- 112. (Previously Presented) A method according to claim 111, wherein said hair loss is selected from the group consisting of androgenic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

(Cancelled) 113 - 114.

- 115. (Previously presented) A method comprising topically administering a composition according to claim 62 to a region of hair loss on a patient.
- (Previously Presented) A method according to claim 115, wherein said hair loss is 116. selected from the group consisting of androgenic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

117 - 122. (Cancelled)

(Currently Amended) A composition in the form of a single-phase gel consisting 123. essentially of:

from about 5% to about 8% of minoxidil;

from about 30% to about 80% of a first solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol;

from about 10% to about 50% of a second solvent selected from the group consisting of ethanol, propanol and butanol;

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from about 0.01% to about 50% of a crosslinked copolymer of acrylic acid; from about 0% to about 3% of a neutralizing agent;

optionally, one or more pharmaceutically acceptable additives or ingredients selected from the group consisting of hair conditioners, panthenol, calcium pantothenate, colorants, fragrances, vitamin E, penetration modifiers, surfactants, cosmetic agents, fatty acids and fatty acid esters, herbal extracts, henna, emulsifiers, wetting agents, sunscreens, and anti-irritants; and

water (qs);

wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition.

- 124. (**Previously Presented**) A composition of claim 123, wherein said first solvent is propylene glycol.
- 125. (**Previously Presented**) A composition of claim 123, wherein said second solvent is selected from the group consisting of ethanol and isopropanol.
- 126. (**Previously Presented**) A composition of claim 123, wherein said crosslinked copolymer of acrylic acid is an acrylate/ C_{10-30} alkyl acrylate crosspolymer.
- 127. (**Previously Presented**) A composition of claim 123, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.

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128. (**Previously Presented**) A composition of claim 127, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine, and mixtures thereof.

129. (**Previously Presented**) A composition of claim 128, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.

130. (Previously Presented) A composition of claim 123, comprising:

from about 5% to about 7% of minoxidil;

from about 40% to about 70% of said first solvent;

from about 20% to about 30% of said second solvent; and

from about 0.05% to about 3% of a crosslinked copolymer of acrylic acid.

131. (**Previously Presented**) A composition of claim 130, comprising:

from about 5% to about 6% of minoxidil;

from about 50% to about 60% of said first solvent; and

from about 25% to about 30% of said second solvent.

132. (Previously Presented) A composition of claim 131 comprising:

about 5% of minoxidil;

about 53% of said first solvent;

about 26% of said second solvent; and

from about 0.25% to about 1% of a crosslinked copolymer of acrylic acid.

- 133. (**Previously Presented**) A method comprising topically administering a composition according to claim 123 to a region of hair loss on a patient.
- 134. (**Previously Presented**) A method according to claim 133, wherein said hair loss is selected from the group consisting of androgenic alopecia, frontal hair loss, bitemporal

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recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.